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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RAO, MANJUNATH N	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,543	LAM ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-9 and 14-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-9,14-18,21,22,24-30 and 32-55* is/are rejected.

7)☒ Claim(s) *19,20,23 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2-8-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-2, 4-9, 14-55 are currently pending and are present for examination.

Applicants' amendments and arguments including the Declaration by Dr. Short and a colored photograph filed on 1-21-05, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Specifically, Examiner has withdrawn the previous objections due to non-compliance of Sequence Rules, due to new matter issues and rejections under 35 U.S.C. 112, 2nd paragraph in view of claim amendments and show of support by the applicant for claims objected as comprising new matter. Examiner has withdrawn the rejection of claim 31 under 35 U.S.C. 112, 1st paragraph for lack of written description in view of persuasive arguments. Examiner has withdrawn the previously held rejection under 35 U.S.C. 102(e) in view of persuasive arguments.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 53 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 53 is simply drawn to a "host cell comprising a nucleic acid having a sequence set forth in claim 37" which reads on any natural cell comprising in its genomic material a sequence set forth in claim 37 which is a nucleic acid sequence encoding a endoglucanase activity. Amending the claim to recite "a host cell transformed with nucleic acid

having a sequence set forth in claim 37" to show the hand of man would overcome the above rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-9, 14-18, 21-22, 24-30, 32-34, 38-52, 55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an endoglucanase of SEQ ID NO:46, a polynucleotide having the SEQ ID NO:45 encoding the same and vectors and host cells comprising said polynucleotide, does not reasonably provide enablement for any such polypeptide that has either 70%, 90%, 95%, or 97% sequence identity with SEQ ID NO:46 or polypeptides comprising 30 or 50 amino acids of a polypeptide that is 70% identical to SEQ ID NO:46 or cellulase polypeptides comprising 30 or 50 consecutive amino acids of SEQ ID NO:46 or a polynucleotide having a nucleotide sequence which is either 70%, 90%, 95%, 97% identical to SEQ ID NO:45 or a probe comprising 15, 25, 35, or 50 nucleotides of a polynucleotide having a sequence that is at least 70% identical to SEQ ID NO:45, vectors and host cells comprising said polynucleotides and method of making said polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1)

the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1, 2, 4-9, 14-18, 21-22, 24-30, 32-34, 38-52, 55 are so broad as to encompass any endoglucanase polypeptide that has either 70%, 90%, 95%, or 97% sequence identity with SEQ ID NO:46 or polypeptides comprising 30 or 50 amino acids of a polypeptide that is 70% identical to SEQ ID NO:46 or cellulase polypeptides comprising 30 or 50 consecutive amino acids of SEQ ID NO:46 or a polynucleotide having a nucleotide sequence which is either 70%, 90%, 95%, 97% identical to SEQ ID NO:45 or a probe comprising15, 25, 35, or 50 nucleotides of a polynucleotide having a sequence that is at least 70% identical to SEQ ID NO:45, vectors and host cells comprising said polynucleotides and method of making said polypeptides. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides and polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only a single endoglucanase. It would require undue experimentation of the skilled artisan to make and use the claimed

polypeptides and polynucleotides. The specification is limited to teaching the use of SEQ ID NO: 45 and 46 as a endoglucanase but provides no guidance with regard to the making of variants and mutants or with regard to other uses. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any endoglucanase polypeptide and polynucleotide encoding the same because the specification does not establish: (A) regions of the protein structure which may be modified without affecting its activity; (B) the general tolerance of endoglucanases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying

any amino acid residue with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including endoglucanases with an enormous number of amino acid modifications to SEQ ID NOS:46. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptide having endoglucanase activity and the polynucleotides encoding the same is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the previous Office action, applicants have traversed the above rejection arguing at length that the specification enables those skilled in the art at the time the invention was made to identify and make and use a genus of polypeptides having endoglucanse or cellulase activity and the nucleic acids that encode them to practice the claimed invention. In support of such an argument applicant has also provided a Declaration by Dr. Short. Applicant, while arguing that the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention, asserts that the references provided by the Examiner in support of the rejection are not specifically directed to the polypeptides and their variants claimed herein. Applicant also points out that the Office makes an unsupported allegation that it was not routine in the art to screen for multiple substitutions and modifications

in a sequence and provides Dr. Short's declaration to show that such was not the case in the prior art. Examiner respectfully disagrees with all of the above arguments. First of all Examiner reiterates that applicants are claiming an extremely large genus of polypeptides and polynucleotides that encode such polypeptides without ample support in the specification for the same. Furthermore, the reference provided by the Examiner is a general reference to show the state of understanding of effects of modifying amino acid residues in a polypeptide sequence. Those references do show that random changes in a given polypeptide does not always lead to a variant having the original function. Irrespective of the arguments and comments by the applicant regarding those references the above fact (i.e., random changes in a given polypeptide does not always lead to a variant having the original function) is well recognized in the art. Examiner does acknowledge that the art has evolved to great heights, that it is now possible to set up high through-put assays to determine the activity of any given set of polypeptides. However, the crux of this enablement rejection is not the determination of the activity of the variant sequences. The crux of this enablement rejection is the lack of guidance for making the variant sequences, i.e., specific guidance as to which amino acid/nucleotide can be modified or replaced with which other amino acid/nucleotide. Examiner has rejected the claims because applicants have not provided specific guidance for making specific changes in the polypeptide/polynucleotide sequence without which those skilled in the art would be subject to undue experimentation. In response to the above position of the Examiner, applicants have traversed and maintain that it would not have been necessary for one skilled in the art to understand which specific regions of enzyme structure could be modified to generate the claimed genus of polypeptides without undue experimentation, and that such information was, inter alia,

readily available in the form of endoglucanase and cellulase sequences known in the art at the time of the invention and a routine, simple sequence alignment comparison of known endoglucanase and cellulase sequences would have identified regions of identity and dissimilarity to provide guidance to the skilled artisan as to which sequences could be changed, or not changed, to generate structural and/or functional variations of an exemplary ***endonucleases*** (?) of the invention (not clear to the Examiner regarding the relationship between an endoglucanase/cellulase and an endonuclease). Applicant provides a sequence alignment of a random selection of endoglucanases and cellulases known in the art at the time of the invention (e.g., sequences including the exemplary SEQ ID NO:45 of the invention), and argues that regions of common structural identity between endoglucanases and cellulases were readily identifiable and thus, if the skilled artisan desired some guidance as to which amino acid residues could be modified to obtain structural or functional variants of an enzyme of the invention, that information was readily available at the time of the invention. Applicant also argues that further guidance regarding the structure and active sites are also readily available by way of crystal structure and therefore, while not necessary, but if desired, one skilled in the art had many sources of guidance. Examiner respectfully disagrees with such an argument. This is because while those skilled in the art can align sequences and identify those regions that are conserved and regions that are not conserved, the total number of changes that need to be made even in the non-conserved regions would be so large that in the absence of specific guidance as to which specific amino acid residue or nucleotide can be modified with which other amino acid or nucleotide it would lead to undue experimentation.

Examiner reiterates that while it can be argued that methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan and even if such methods are routine, producing variants as claimed by applicants requires that one of ordinary skill in the art know or be provided with specific guidance for the selection of specific amino acid or nucleotide residue that can be modified with which other amino acid or nucleotide and which among the extremely large number of variants have the claimed property (i.e., endoglucanase activity). Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a specific guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does not establish: (A) regions of the protein structure which may be modified without affecting its activity; (B) the general tolerance of endoglucanases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Therefore the above rejection is maintained.

Claims 27-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of polypeptides having endoglucanase activity and comprising 30 or 50 amino acids of a polypeptide that has 70% sequence identity to SEQ ID NO:46 or 30 to 50 amino acids of SEQ ID NO:46. The specification does not contain any disclosure of the structure of all such sequences included in the claimed genera. The genus of polypeptides claimed is a large variable genus with the potentiality of having different structures. Therefore, many structurally distinct polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus (i.e., that of SEQ ID NO:46) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. A sufficient written description of a genus of polypeptides may be achieved by a recitation of a representative number of polypeptides defined by sequence or a recitation of structural features common to members of the genus, **which features constitute a substantial portion of the genus**. The recited structural feature of the genus (i.e., polypeptides having endoglucanase activity and comprising 30 or 50 amino acids of a polypeptide that has 70% sequence identity to SEQ ID NO:46 or polypeptides comprising 30 to 50 amino acids of SEQ ID NO:46) does not constitute a substantial portion of the genus as the remainder of the structure of such polypeptide having endoglucanase activity is completely undefined and the specification does not define the remaining structural features necessary for members of the genus to be selected. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In response to the above rejection, applicants have traversed. Applicants have also recited several decisions handed down in previous court cases. Examiner does not have the prosecution history of those cases and therefore it is beyond the scope of this Office action to determine whether the fact-pattern of those cases are applicable to the instant case. Apart from that applicants maintain and submit that the claimed invention is sufficiently described in the specification so that one of ordinary skill in the art would be able to ascertain the scope of the claims with reasonable clarity and that applicants were in possession of the claimed invention at the time of filing. Applicants submit that describing a genus of polynucleotides in terms of physico-chemical properties (e.g., a % sequence identity or stringent hybridization to an exemplary nucleic acid or polypeptide, e.g., SEQ ID NO:45 or SEQ ID NO:46) and function (e.g., encoding a polypeptide having endoglucanase/ cellulase activity) satisfies the written description requirement of section 112, first paragraph and that the disclosed endoglucanase/ cellulase species of the claimed invention, SEQ ID NO:45 and SEQ ID NO:46, are sufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genera. Applicants maintain that both the Patent Office and the Federal Circuit set forth conditions where a single species is sufficient to put one of skill in the art in possession of the attributes and features of all species within a genus, where the genus is defined in terms of shared physical and structural properties with the single species.

In response while acknowledging that describing a genus of polynucleotides/polypeptides in terms of physico-chemical properties (e.g., a % sequence identity or stringent hybridization to an exemplary nucleic acid or polypeptide, e.g., SEQ ID NO:45 or SEQ ID NO:46) and function (e.g., encoding a polypeptide having endoglucanase/ cellulase activity) satisfies the written description requirement of section 112, Examiner respectfully disagrees with the argument that instant claims as written satisfies the written description requirement. This is because the structural properties of the claimed polypeptides/polynucleotides provided are not sufficient such that it can be concluded that they are amply described. It should be remembered here that applicants are not claiming polypeptides/polynucleotides that have specific % homology with SEQ ID NO:45 or 46, but are claiming those sequences that comprise a small part of the structure of a large genus of sequences. In view of that it cannot be concluded that the structure of SEQ ID NO:45 or 46 is representative of all the claimed sequences.

Next applicants draw the attention of the Examiner to the Guidelines and argue that instant claims are similar to those in Example 14. Examiner respectfully disagrees. This is because in Example 14, the polypeptides claimed are straight variants that are at least 95% identical to a given sequence with SEQ ID NO:3 and not as claimed here. If the fact-pattern of the instant case was identical to that of Example 14 of the Guidelines, Examiner would not have rejected instant claims. However, the fact-pattern is different. In the instant claims applicants are claiming a polypeptide comprising few amino acids of a sequence that is having a set % homology to SEQ ID NO:45 or 46. Therefore, arguing that the fact-pattern of the instant case is analogous to the fact-pattern presented in example 14 is highly misplaced.

As discussed in the written description guidelines, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. **Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.** Satisfactory disclosure of a representative number depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. In the instant case the claimed genera includes species which are widely variant in structure. The claimed genus encompasses polynucleotides/polypeptides with endoglucanase activity that are structurally diverse. As such, neither the description of the structure and function of SEQ ID NOS:45/46 nor the disclosure solely of functional features present in all members of the genus is sufficient to be representative of the attributes and features of the entire genus. Hence the rejection is maintained.

Claims 40-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules comprising 15, 25, 35, or 50 contiguous nucleotides of a nucleic acid sequence having at least 70% sequence identity to SEQ ID NO:45.

The specification does not contain any disclosure of the function of all DNA sequences that are encompassed by the claim. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In response to the above rejection, applicants maintain that the above claims are described. However, Examiner respectfully disagrees. This is because, claims continue to be drawn to probes "comprising" set number of nucleotides. While it is acknowledged that the probes (of set length as 15, 30 nucleotides etc.) hybridize to SEQ ID NO:45, applicants have

not provided the structure or the function of the nucleotides comprising the probes. It must be noted here that the use of "comprising" language leads those skilled in the art to conclude that the so called "probes" comprise sequences that may or may not hybridize to SEQ ID NO:45. And it is the structure and function of such sequences that applicants have not described. Hence the above rejection is maintained.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 36 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 11 of prior U.S. Patent No. 5,789,228. Claim 36 is drawn to a polynucleotide sequence wherein the polynucleotide has a sequence set forth in SEQ ID NO:45. However, SEQ ID NO:45 is 100% identical to the polynucleotide claimed in claim 11 as SEQ ID NO:1. This is a double patenting rejection. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 4, 5-9, 14, 32-43, 53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No.5,789,228. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 2, 4, 5-9, 14, 32-43, 53 of the instant application and claims 1-11 of the reference patent are both directed to polynucleotides with SEQ ID NO:45 (please refer to previous Office action, where it was shown that SEQ ID NO:45 of the instant application and the SEQ ID NO:1 of the patent was 100% identical). However the instant claims are also directed to variants of SEQ ID NO:45 and vectors and host cells comprising the same. Among all the different variants of SEQ ID NO:45 (which is 100% identical to SEQ ID NO:1 of the patent) claimed in the instant application and the sequence in

the reference patent at least one is identical to one another. The portion of the specification (and the claims) in the reference patent that supports the recited sequence, SEQ ID NO:1 includes several embodiments that would anticipate the variants claimed in claims 2, 4, 5-9, 14, 32-43, 53 herein. Claims 2, 4, 5-9, 14, 32-43, 53 of the instant application listed above cannot be considered patentably distinct over claims 1-11 of the reference patent when there is specifically recited embodiment that would anticipate mainly claims 2, 4, 5-9, 14, 32-43, 53 of the instant application. Alternatively, claims 2, 4, 5-9, 14, 32-43, 53 cannot be considered patentably distinct over claims 1-11 of the reference patent when there is specifically disclosed embodiment in the reference patent that supports claims 1-3 of that patent and falls within the scope of claims 2, 4, 5-9, 14, 32-43, 53 herein because it would have been obvious to one having ordinary skill in the art to modify claims 1-11 of the reference by selecting a specifically disclosed embodiment that supports those claims i.e., a variant of a parent polynucleotide with SEQ ID NO:1 which is 100% identical to SEQ ID NO:45 of the instant application. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1-11 of the reference patent.

Conclusion

Claims 19-20, 23, and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

April 12, 2005